K113304

MAR 2 3 2012

MEDA CO., LTD

AI-5: 510(k) Summary

510(k) SUMMARY

1) Submitter Information

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Contact person: **KAI CHEN**
Medtech International, Inc. and
United States Designated Agent of MEDA Co., Ltd.
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Date Prepared: October 9, 2011

2) Device Information

Trade Name: MD-6000 Bladder Scanner
Common Name: Diagnostic Ultrasound System with Accessories
Classification Name: Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer
Regulation Number: 892.1560, 892.1570
Product Code: IYO, ITX

3) Predicate Devices

For identification of predicate device, we retrieved the legally marketed similar products from FDA's official website and according to the published 510(k) Summary, we selected the following device which has the same intended use and working principle, and is equivalent in structure (including accessories) and technical characteristics as the predicate device:

Manufacturer: Mcube Technology Co., Ltd.
Device: CUBEscan /BioCon-500
510(k) Number: K091518

4) Device Description

MD-6000 Bladder Scanner is a portable battery-operated ultrasonic equipment of pulse reflection. It utilizes ultrasonic distance measuring principle to calculate the bladder volume.

It makes mechanical sector scan by 2.5MHz ultrasonic wave and recognizes the reflected wave of the front and back wall of bladder to get the area information of bladder section. It calculates the volume of bladder by volume integral algorithm on the basis of the area information of 12 reference planes which are changed automatically with an interval of 15° .

MD-6000 Bladder Scanner has a Pre-Scan function, which shows the real-time B mode image for sectional plane of bladder. The Pre-Scan function helps a user to locate the bladder easily and get more accurate results.

Built-in thermal printer provides convenience of printing data.

5) Intended Use

MD-6000 Bladder Scanner is intended to measure the volume of bladder filled with urine.

The MD-6000 is intended to be used only by qualified medical professionals. Contraindications for the MD-6000 are fetal use and use on pregnant patients.

6) Technological Characteristics

a) Safety

Electrical, mechanical, environmental safety testing according to standard IEC 60601-1:1988+A1+A2 and IEC 60601-2-37:2007 was performed.
EMC testing was conducted in accordance with standard IEC 60601-1-2:2007.
All test results meet the requirements of the standard.

The safety standards performed by MD-6000 Bladder Scanner are identical with that of the predicate product.

b) Characteristics

Both MD-6000 and its predicate device are intended to measure the volume of bladder, and their Pre-Scan functions are real-time images for sectional plane of bladder. The measuring range of MD-6000 is 20-999ml and measuring accuracy is 15%, which are substantially equivalent with that of the predicate device.

The main differences of MD-6000 Bladder Scanner and its predicate device are: apart from the slight difference in ultrasound frequency (2.5MHz/2.8MHz), the monitor, housing, battery and battery charger of MD-6000 are in different model, but the safety tests showed that they all meet the requirements.

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While there are some differences between the MD-6000 and its predicate device, they do not affect the safety and effectiveness of the device.

7) Brief Discussion of nonclinical Tests

The safety tests that are based on FDA-recognized standards were conducted by TÜV SÜD Laboratories, and all results comply with the requirements of standards.

The software and essential performance have passes verification and validation, and the results comply with the requirements.

8) Brief Discussion of Clinical Evaluation and Validation

The clinical data of Bladder Scanner have been collected and evaluated.

As part of the design validation, we have made validation to the measuring accuracy of bladder volume to 10 volunteers, with the method of comparing the measuring value and the actual volume of excreted urine. Moreover, we have entrusted professional doctors to make clinical effectiveness tests in medical environments. The clinical test results showed that MD-6000 Bladder Scanner met the requirements of intended clinical applications.

No adverse effect was found during the collection and evaluation of clinical data and clinical validation.

9) Conclusions

The results of nonclinical tests as well as clinical evaluation and validation demonstrate that the MD-6000 Bladder Scanner is equivalent in safety, effectiveness and performance to the legally marketed predicate device.

MEDA CO., LTD will update and include in this summary any other information deemed reasonably necessary by the FDA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 2 3 2012

MEDA. Co., Ltd.
% Mr. Kai Chen
United States Designated Agent
Medtech International, Inc.
13505 Broadfield Drive
POTOMAC MD 20854

Re: K113304
Trade/Device Name: MD-6000 Bladder Scanner
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 1, 2012
Received: March 1, 2012

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113304

Device Name: MD-6000 Bladder Scanner

Indications For Use:

MD-6000 Bladder Scanner is a portable battery-operated ultrasonic equipment of pulse reflection. It is intended to measure the volume of bladder filled with urine.

The **MD-6000** is intended to be used only by qualified medical professionals. Contraindications for the **MD-6000** are fetal use and use on pregnant patients.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Concurrence of CDRH, Office of Device Evaluation (ODE)

510K K113304